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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,206	08/05/2003	Russell Powers	4002-3357/PC934.00	6826
52196	7590	09/29/2005	EXAMINER	
KRIEG DEVAULT LLP			PELLEGRINO, BRIAN E	
ONE INDIANA SQUARE, SUITE 2800			ART UNIT	
INDIANAPOLIS, IN 46204-2709			PAPER NUMBER	

3738

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/634,206

Applicant(s)

POWERS ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 40-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/5/03, 1/10/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I in the reply filed on 7/13/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 40-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29,32,39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 recites "the surgical kit is self-contained to include **all** surgical equipment required to perform a designated spinal surgery". It is not clear what is meant by "self-contained" and the meaning of "all surgical equipment". Does this mean other equipment not shown or disclosed? Or just the equipment disclosed?

Claim 32 recites the screws are "variable-angle screws". However, it is not clear what is meant by this limitation. Does it mean the screws are positioned at an angle or the threads are angled?

Claim 39 recites the limitation "said instrumentation" in lines 5 and 6 of the claim. There is insufficient antecedent basis for this limitation in the claim. Did Applicant mean to recite "said driver instrument"?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,2,5,6,8,9,21,26,27,29 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Banick et al. (2003/93153). Fig. 7 shows a surgical kit **60** for use in spinal surgery comprising a spinal implant **20**, instrumentation **52** for use in the surgery, a template or instructions **64** and packaging **66** to contain the kit in a sterilized condition prior to surgery. The implant is fully capable of engagement between first and second vertebrae. Banick et al. disclose that a bone growth material can be used in the intervertebral space for fusion, paragraph 40. The instrumentation is fully capable of being used in a single surgery or a limited number of surgeries. Banick also discloses

the template or instructions can be provided external to the packaging to maintain sterile conditions for the implant, paragraph 37.

Claims 1,2,5-9,17,20,21,29 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner et al. (5306309). Wagner et al. show (Fig. 3) a spinal implant **50** for a kit. Wagner discloses the implant is packaged and sterilized, col. 2, lines 60,61. Wagner also discloses the surgical kit is packaged and contains instrumentation with the spinal implant, col. 2, lines 65-68. Wagner discloses the implant can have bone growth promoting substances thereon for causing fusion between vertebrae, col. 6, lines 37-45. Wagner additionally discloses the instrument is used and designed for planned disposal, col. 4, lines 9,10.

Claims 1-4,17,30,36,37,39 are rejected under 35 U.S.C. 102(b) as being anticipated by Henniges et al. (2002/107574). Fig. 1 shows a surgical plate **10** and a number of bone screws **12** to secure the plate. Fig. 11A shows a driver instrument **24** with a shaft portion **372** and a handle portion **15** to drive the screws into bone. It can be construed that the handle has a first portion **54** rotatably coupled to a second portion **42** to provide relative rotational movement along the longitudinal axis. Henniges et al. disclose the equipment is packaged, paragraph 60. It is inherent the surgical kit is maintained in sterile conditions, since doctors will not risk using unsterile equipment on a patient, which could cause infections. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Clearly the implant is capable of being used as a spinal implant.

Claim Rejections - 35 USC § 103

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banick et al. (2003/93153) in view of Paikoff et al. (4523679). Banick is explained supra. However, Banick fails to disclose a plurality of compartments to hold the kit components or that there is an inner and outer container to maintain sterility or that the packaging is clear. Paikoff et al. show packaging for medical instrumentation with a plurality of compartments. Paikoff also teaches that the packaging is formed with an inner and outer container, col. 3, lines 55-65, col. 4, lines 38-43. It is also well known that the plastic is clear such that the surgeon can see what is in the package. Paikoff additionally teaches that the different compartments are used to allow for different sterilized products, col. 3, lines 42-45, 65-68. It would have been obvious to one of ordinary skill in the art to use multi compartments as taught by Paikoff to package the spinal kit of Banick so that no damage is done to the different components of the kit while packaged and sterilized under sterilization procedures.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banick et al. (2003/93153). It would have been an obvious matter of design choice to modify the template or instructions to have an indication of a magnification factor, since applicant has not disclosed that using the particular template provided provides any advantage, or solves a stated problem, or is used for any particular purpose. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the template or instructions taught by Banick et al. or the claimed template with a magnification factor in claim(s) 28 because both kits perform

the same function of providing the surgeon with a spinal implant and tool having a template to utilize the kit.

Claims 10-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. '309 in view of Guttag (5346929). Wagner et al. is explained supra. However, Wagner et al. fail to disclose the instrumentation is subject to degradation upon exposure to sterilization. Wagner does disclose the tool is made of a plastic, col. 3, lines 62,63. Guttag teaches that the number of plastic devices disposed of have caused a problem in the environment and there is a need for biodegradable plastics, col. 1, lines 15-28,35,36. Guttag also teaches that biodegradable plastics are used to make many different devices, including medical instruments such as syringes (col. 2, lines 27,28,53,54, col. 3, line 44). Guttag additionally teaches that the plastics are subjected to high temperatures and that exposure to moisture causes degradation, col. 2, lines 60-66, col. 3, lines 36-38. It would have been obvious to one of ordinary skill in the art to use a biodegradable plastic as taught by Guttag for the plastic instrument of Wagner such that it can easily be disposed of. It is also well known that autoclaving the instrument involves the use of moisture or steam to sterilize and thus when sterilizing and thus would cause the degradation of the plastic since it has been exposed to moisture. It is also inherent that as degradation occurs it begins to deform and can be become discolored and becomes substantially inoperative.

Claims 18,19,38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henniges et al. (2002/107574) in view of Sweeny (5901622). Henniges et al. is explained as before. However, Henniges et al. fail to disclose the shaft being

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reversible. Sweeny shows (Fig. 4) a reversible shaft with two different tip sizes. Sweeny also teaches that the use of reversible shafts provides multiple functions, which is advantageous, col. 1, lines 23-27. It would have been obvious to one of ordinary skill in the art to use a reversible shaft as taught by Sweeny with the instrument of Henniges such that the surgeon is able to use the same instrument without having to get another instrument when adjusting for different size screws. A substitution of screw heads is well within one of ordinary skill in the art knowledge.

Claims 31,32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henniges et al. (2002/107574) in view of Wolter (6322562). Henniges et al. is explained as before. However, Henniges et al. fail to disclose the bone screws as self-cutting or variable-angle. With respect to claim 32, as best understood, Wolter shows (Figs. 2a-2i) the bone screw can be variable-angle. Wolter also teaches that self-cutting bone screws are used such that they eliminate the use of additional tools in the surgery, col. 4, lines 4-13. It would have been obvious to one of ordinary skill in the art to utilize self-cutting bone screws with the implant of Henniges such that the surgeon does not have to perform additional procedures such as drilling using more tools and thus reducing the time for the surgery.

Claims 30,33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pisharodi (6610093) in view of Wagner et al. '309. Pisharodi shows (Fig. 1) a surgical kit comprising spinal plates **34**, a number of bone screws **30** and an interbody implant **26**. It is inherent that a driver instrument would be used to drive the bone screws in the vertebrae and that the surgical equipment would be packaged and maintained sterile for

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the surgeon to use in a patient. However, Pisharodi fails to disclose the equipment as a set and that the instrument would be disposed of or degrades. Wagner et al. is explained supra. It would have been obvious to one of ordinary skill in the art to use a packaged kit as taught by Wagner for the surgical equipment of Pisharodi such that it reduces the number of packages required in the surgery and allows the surgeon to dispose of used instrumentation to eliminate the risk of causing infection. Any portion of a plastic instrument is subject to degradation because the material is subjected to extreme temperatures or caustic compounds used to sterilize the device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (6:30am-4pm) and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

A handwritten signature in cursive script that reads "Brian E. Pellegrino". The signature is written in black ink and is positioned below the printed name and title.